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| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 10/773,596             | MILLS, ALEXANDER K. |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | Patricia C. Mallari    | 3736                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicant's amendment filed 12/27/04.
2. ☒ The allowed claim(s) is/are 13, 19, 26 and 27.
3. ☒ The drawings filed on 2/6/04 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### REASONS FOR ALLOWANCE

Claims 13, 19, 26, and 27 are allowed. The allowability of claims 13 and 19 was addressed in a previous Office action filed 12/10/04. A portion of that discussion is repeated below.

The following is an examiner's statement of reasons for allowance:

US Patent No. 5,542,421 to Erdman and US Patent No. 6,120,459 to Nitzan et al. represent the most relevant prior art for the claims of this application.

US Patent No. 5,542,421 to Erdman discloses a method for measuring circulatory conditions wherein a first and a second tissue probe 10 are provided, each probe having a radiation emitter 20 and detector 30 (figs. 1 & 11; col. 6, line 64-col. 7, line 2; col. 10, lines 58-61 of Erdman). The first tissue probe 10 is placed proximate a first extremity of the patient, and the second 10 is provided on a second opposing extremity (fig. 11). First and second extremities are placed in a plurality of positions, and the absorbance of the blood is continually measured at each position by the first and second probes 10 (fig. 11; col. 10, lines 62-64; col. 11, line 32-col. 12, line 24).

Erdman lacks placing an extremity carrying a tissue probe at a first probe position relative to a level corresponding to the patient's heart, comparing the rate of change of absorbance at the second position of the extremity with said first probe position absorbance to determine at least a first rate of change of absorbance value, and determining central venous drainage from the rate of change of absorbance value. With regard to claims 13 and 19, Erdman also lacks computing a blood parameter at the first probe position based on the first probe position absorbance,

US Patent No. 6,120,459 to Nitzan et al. discloses a method of measuring blood pressure wherein a tissue probe having a first radiation emitter and detector is placed proximate an extremity of a patient (col. 9, lines 5-15 of Nitzan). The absorbance of the patient's blood is measured by the probe and a blood parameter is determined therefrom (col. 8, lines 44-61 of Nitzan). However, there is no suggestion to combine the method of Nitzan with that of Erdman.

US Patent No. 3,585,987 to Svenson teaches a method of measuring a blood parameter in an extremity of a patient's body, wherein the extremity is placed at the level of the heart during the time of measurement in order to obtain a more accurate measurement (col. 3, lines 19-23 of Svenson). While it would have been obvious to place at least one extremity at heart level during the method of Erdman in light of the teaching in Svenson that such placement ensures more accurate readings, the combination would still fail to teach comparing the rate of change of absorbance at the second extremity position with the first probe position absorbance to determine at least a first rate of change of absorbance value, and determining central venous drainage from the rate of change of absorbance values.

Regarding claims 13 and 19, the prior art of record fails to teach or fairly suggest a method wherein central venous drainage is determined from a rate of change of absorbance values at each of a plurality of extremity positions to which an extremity, on which a probe is placed, is moved, comprising any of the steps of computing a blood parameter at the first probe location based on the first probe position absorbance, moving the extremity to a plurality of extremity positions relative to the first probe

location, or comparing the rate of change of absorbance at each of the plurality of extremity positions with the first probe position absorbance to determine a plurality of rate of change of absorbance values, in combination with all of the other limitations of the claims.

Regarding claims 26 and 27, the prior art of record fails to teach or fairly suggest a method for noninvasively determining a patient's cardiac output, wherein central venous drainage of a patient is determined from a rate of change of absorbance values, which is determined by determining the rate of change of the absorbance of a patient's blood absorbance, using a probe having a radiation emitter and a detector, at each of a plurality of levels of the patient's extremity, relative to the patient's blood absorbance in the opposing extremity placed at a level coincident with the patient's heart, in combination with all of the other limitations of the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

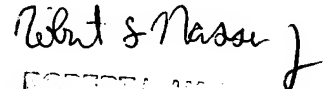
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia Mallari  
Patent Examiner  
Art Unit 3736

  
ROBERT S. NASSAR  
PATENT EXAMINER